



4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project “**Medical Office Survey on Patient Safety Culture Database.**”

DATES: Comments on this notice must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION].

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Medical Office Survey on Patient Safety Culture Database

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection. In 1999, the Institute of Medicine called for health care organizations to develop a “culture of safety” such that their workforce and

processes focus on improving the reliability and safety of care for patients (IOM, 1999; *To Err is Human: Building a Safer Health System*). To respond to the need for tools to assess patient safety culture in health care, AHRQ developed and pilot tested the Medical Office Survey on Patient Safety Culture with OMB approval (OMB NO.0935-0131; Approved July 5, 2007).

The survey is designed to enable medical offices to assess provider and staff perspectives about patient safety issues, medical error, and error reporting. The survey includes 38 items that measure 10 composites of patient safety culture. In addition to the composite items, 14 items measure staff perceptions of how often medical offices have problems exchanging information with other settings as well as other patient safety and quality issues. AHRQ made the survey publicly available along with a Survey User's Guide and other toolkit materials in December, 2008 on the AHRQ Web site (located at <https://www.ahrq.gov/sops/quality-patient-safety/patientsafetysafetyculture/medical-office/index.html>).

The AHRQ Medical Office SOPS Database consists of data from the AHRQ Medical Office Survey on Patient Safety Culture and may include reportable, non-required supplemental items. Medical offices in the U.S. can voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The Medical Office SOPS Database (OMB NO. 0935-0196, last approved on August 25, 2015) was developed by AHRQ in 2011 in response to requests from medical offices interested in tracking their own survey results. Those organizations submitting data receive a feedback report, as well as a report of the aggregated, de-identified findings of the other medical offices submitting data. These reports are used to assist medical office staff in their efforts to improve patient safety culture in their organizations.

Rationale for the information collection. The Medical Office SOPS and the Medical Office SOPS Database support AHRQ's goals of promoting improvements in the quality and safety of health care in medical office settings. The survey, toolkit materials, and database results are all made publicly available on AHRQ's Web site. Technical assistance is provided by AHRQ through its contractor at no charge to medical offices, to facilitate the use of these materials for medical office patient safety and quality improvement.

Request for information collection approval. The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) reapprove, under the

Paperwork Reduction Act of 1995, AHRQ's collection of information for the AHRQ Medical Office SOPS Database; OMB NO. 0935-0196, last approved on August, 25, 2015.

This database will:

- 1) Present results from medical offices that voluntarily submit their data,
- 2) Provide data to medical offices to facilitate internal assessment and learning in the patient safety improvement process, and
- 3) Provide supplemental information to help medical offices identify their strengths and areas with potential for improvement in patient safety culture.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to: the quality, effectiveness, efficiency, appropriateness and value of health care services; quality measurement and improvement; and database development. 42 U.S.C. 299a(a)(1), (2), and (8).

Method of Collection

To achieve the goal of this project the following activities and data collections will be implemented:

- 1) **Eligibility and Registration Form** – The medical office point-of-contact (POC) completes a number of data submission steps and forms, beginning with the completion of an online Eligibility and Registration Form. The purpose of this form is to collect basic demographic information about the medical office and initiate the registration process.
- 2) **Data Use Agreement** – The purpose of the data use agreement, completed by the medical office POC, is to state how data submitted by medical offices will be used and provide privacy assurances.
- 3) **Medical Office Site Information Form** – The purpose of the site information form, also completed by the medical office POC, is to collect background characteristics of the medical

office. This information will be used to analyze data collected with the Medical Office SOPS survey.

4) **Data Files Submission** – POCs upload their data file(s), using the medical office data file specifications, to ensure that users submit standardized and consistent data in the way variables are named, coded, and formatted. The number of submissions to the database is likely to vary each year because medical offices do not administer the survey and submit data every year. Data submission is typically handled by one POC who is either an office manager or a survey vendor who contracts with a medical office to collect their data. POCs submit data on behalf of 35 medical offices, on average, because many medical offices are part of a health system that includes many medical office sites, or the POC is a vendor that is submitting data for multiple medical offices.

Survey data from the AHRQ Medical Office Survey on Patient Safety Culture are used to produce three types of products:

- 1) A Medical Office SOPS Database Report that is made publicly available on the AHRQ Web site (see Medical Office User Database Report);
- 2) Individual Medical Office Survey Feedback Reports that are customized for each medical office that submits data to the database; and
- 3) Research data sets of individual-level and medical office-level de-identified data to enable researchers to conduct analyses. All data released in a data set are de-identified at the individual-level and the medical office-level.

Medical offices will be invited to voluntarily submit their Medical Office SOPS survey data to the database. AHRQ's contractor, Westat, then cleans and aggregates the data to produce a PDF-formatted Database Report displaying averages, standard deviations, and percentile scores on the survey's 38 items and 10 patient safety culture composites of patient safety culture, and 14 items measuring how often medical offices have problems exchanging information with other settings and other patient safety and quality issues. The report also displays these results by medical office characteristics (size of office, specialty, geographic region, etc.) and respondent characteristics (staff position).

The Database Report includes a section on data limitations, emphasizing that the report does not reflect a representative sampling of the U.S. medical office population. Because participating medical offices will choose to voluntarily submit their data into the database and therefore are not a random or national sample of medical offices, estimates based on this self-selected group might be biased estimates. We recommend that users review the database results with these caveats in mind.

Each medical office that submits its data receives a customized survey feedback report that presents their results alongside the aggregated results from other participating medical offices.

Medical offices use the Medical Office SOPS, Database Reports, and Individual Medical Office Survey Feedback Reports for a number of purposes, to:

- Raise staff awareness about patient safety;
- Elucidate and assess the current status of patient safety culture in their medical office;
- Identify strengths and areas for patient safety culture improvement;
- Evaluate trends in patient safety culture change over time; and
- Evaluate the cultural impact of patient safety initiatives and interventions.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in the database. An estimated 70 POCs, each representing an average of 35 individual medical offices each, will complete the database submission steps and forms. Each POC will submit the following:

- Eligibility and registration form (completion is estimated to take about 3 minutes).
- Data Use Agreement (completion is estimated to take about 3 minutes).
- Medical Office Information Form (completion is estimated to take about 5 minutes).
- Survey data submission will take an average of one hour.

The total burden is estimated to be 283 hours.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be \$14,880 annually.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Eligibility/Registration Form	70	1	3/60	4
Data Use Agreement	70	1	3/60	4
Medical Office Information Form	70	35	5/60	205
Data Files Submission	70	1	1	70
Total	NA	NA	NA	283

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Registration Form	70	4	\$ 52.58	\$210
Data Use Agreement	70	4	\$ 52.58	\$210
Medical Office Information Form	70	205	\$ 52.58	\$10,779

Data Files Submission	70	70	\$ 52.58	\$3,680
Total	NA	213	NA	\$14,880

* Mean hourly wage rate of \$52.58 for Medical and Health Services Managers (SOC code 11-9111) was obtained from the May 2016 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 621100 - Offices of Physicians located at <https://www.bls.gov/oes/current/oes119111.htm>.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Francis D. Chesley, Jr.,
Acting Deputy Director.